IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. ALKEM LABORATORIES LIMITED, Defendant.	C.A. No. _____

PLAINTIFFS SUMITOMO DAINIPPON PHARMA CO., LTD. AND SUNOVION PHARMACEUTICALS INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs"), for their complaint against Defendant Alkem Laboratories Limited (collectively, "Defendant" or "Alkem"), allege as follows:

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 9,815,827 (the "'827 patent") and 9,907,794 (the "'794 patent") (collectively, the "Asserted Patents") under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. §§ 271 (a), (b), and (c) relating to Plaintiffs' commercially successful product, Latuda®. A true and accurate copy of the '827 patent is attached hereto as Exhibit A. A true and accurate copy of the '794 patent is attached hereto as Exhibit B.

THE PARTIES

2. Plaintiff Sumitomo is a company organized and existing under the laws of Japan, with a principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

3. Plaintiff Sunovion is a corporation organized and existing under the laws of Delaware, with a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

4. On information and belief, Defendant Alkem is a company organized and existing under the laws of India with a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, India.

5. On information and belief, Alkem is in the business of developing, manufacturing, distributing and selling generic drugs throughout the United States, including in the District of New Jersey. On further information and belief, Alkem is working to achieve final approval by the U.S. Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 212244.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.*, including §§ 271(e)(2), 271(a), 271(b), 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Alkem by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Alkem regularly and

continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. On information and belief, Alkem derives substantial revenue from the sale of pharmaceutical products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Plaintiffs have been injured in New Jersey because of Alkem's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

8. On information and belief, Alkem also owns, directly or indirectly, Ascend Laboratories, LLC ("Ascend") and The Pharma Network, LLC ("Pharma Network"). On information and belief, Ascend and Pharma Network are subsidiaries and/or affiliates of Alkem.

9. On information and belief, Ascend is incorporated under the laws of the state of New Jersey, with places of business at 180 Summit Avenue, Suite 200, Montvale, New Jersey 07645 and 339 Jefferson Road, Suite 101, Parsippany, New Jersey 07054. On information and belief, Ascend is registered to do business in the state of New Jersey (Entity ID No. 0600158194). On information and belief, Ascend is registered with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals (Reg. No. 5003567). On information and belief, Ascend manufactures and/or distributes pharmaceuticals throughout the United States on behalf of Alkem. Ascend's website states that "today Ascend is a wholly owned subsidiary of Alkem taking advantage of Alkem's strong infrastructure and R&D to fuel growth from being a strong startup to an important generic manufacturer and provider suppling [*sic*] it's [*sic*] now over 100 SKU's to Hospitals, Pharmacies and Wholesalers thought [*sic*] the USA." (*See* https://www.ascendlaboratories.com/Home/Background) (last visited October 9, 2018).)

10. On information and belief, Pharma Network is incorporated under the laws of the state of New Jersey, with places of business at 180 Summit Avenue, Suite 200, Montvale, New

Jersey 07645 and 339 Jefferson Road, Suite 101, Parsippany, New Jersey 07054. On information and belief, Pharma Network is registered to do business in the state of New Jersey (Entity ID No. 0600087295). On information and belief, Pharma Network is registered with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals (Reg. No. 5002822).

11. Further, this Court has personal jurisdiction over Alkem because Alkem has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Alkem intends a future course of conduct that includes acts of patent infringement in New Jersey. On information and belief, Alkem, either directly or through its subsidiaries, agents, and/or affiliates, manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including New Jersey. On information and belief, Alkem developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Alkem filed ANDA No. 212244, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including New Jersey.

12. On information and belief, Alkem intends to market its generic lurasidone hydrochloride tablets in New Jersey upon final approval of such products by the FDA.

13. On information and belief, Alkem's conduct has or will cause foreseeable harm and injury to Plaintiffs.

14. Additionally, Sunovion operates a facility in Fort Lee, New Jersey where it engages in, for example, administrative, regulatory, clinical development, medical affairs, and other research and development functions related to numerous pharmaceutical products, including Sunovion's product at issue in this case, Latuda®. Sunovion employs approximately 100 individuals in New Jersey, more than in any other U.S. state, except Massachusetts. Were

Alkem to sell or offer to sell its proposed generic lurasidone hydrochloride products, Plaintiffs will be injured specifically in New Jersey.

15. Further, this Court has personal jurisdiction over Alkem because Alkem has previously been sued in this district and has not challenged personal jurisdiction, and Alkem has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g.*, *Celgene Corp. v. Alkem Labs. Ltd.*, 3:18-cv-11265 (D.N.J.); *Otsuka Pharm. Co., Ltd. v. Alkem Labs. Ltd.*, 1:15-cv-8305 (D.N.J.); *AstraZeneca AB v. Alkem Labs. Ltd.*, 3:15-cv-6609 (D.N.J.).

16. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alkem, this Court may exercise jurisdiction over Alkem pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alkem would be a foreign defendant not subject to personal jurisdiction in the courts of any State; (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling pharmaceutical products that are distributed throughout the United States; and (d) Alkem filed an ANDA with the FDA and sent notice of its Paragraph IV certification to an entity in New Jersey, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

17. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

18. Venue is proper in this district under 28 U.S.C. § 1400(b) because Alkem "committed an act of infringement" in this district. On information and belief, Alkem submitted ANDA No. 212244 pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetics Act ("FFDCA") (codified at 21 U.S.C. § 355(j)), and, upon receiving final approval of such ANDA, will manufacture, sell, offer to sell, and/or import Alkem's proposed generic lurasidone

hydrochloride tablets in the United States, including in the District of New Jersey. Thus, Alkem has committed an act of infringement in this district.

19. Venue is proper in this district under 28 U.S.C. § 1400(b) because Alkem's subsidiaries, Ascend and Pharma Network, reside in New Jersey. Further, venue is proper in this district because Alkem has a "regular and established place of business" in this district. Alkem's subsidiaries, Ascend and Pharma Network, have places of business at 180 Summit Avenue, Suite 200, Montvale, New Jersey 07645 and 339 Jefferson Road, Suite 101, Parsippany, New Jersey 07054. Further, venue is proper in this district because Alkem's subsidiary, Ascend, is registered to do business in the state of New Jersey (Entity ID No. 0600158194), and is registered with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals (Reg. No. 5003567). Further, venue is proper in this district because Alkem's subsidiary, Pharma Network, is registered to do business in the state of New Jersey (Entity ID No. 0600087295), and is registered with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals (Reg. No. 5002822).

20. The Court has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Plaintiffs and Defendant of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Asserted Patents.

FACTUAL BACKGROUND

Background of the '827 Patent Invention

21. Antipsychotic drug products are used in the management of psychotic symptoms associated with disorders including schizophrenia and bipolar disorder. *See, e.g.*, '827 patent col. 1 ll.47-49.

22. Conventional drug product treatments for psychotic symptoms were known to cause unwanted serious side effects. *See, e.g.*, '827 patent col. 1 ll.57-63.

23. Weight gain is a well-known side effect of conventional antipsychotic drug products. *See, e.g.*, File History of U.S. Application No. 14/471,919, Notice of Allowance dated 2017-07-17 ("Notice of Allowance") at 2 ("[C]onventional antipsychotic drug[s] cause[] serious side effects such as undesired metabolic changes . . . which were considered as closely linked with a weight gain."); *see also* Latuda® Prescribing Information (03/2018) at Section 5.6 ("Atypical antipsychotic drugs have been associated with metabolic changes . . . includ[ing] . . . weight gain." . . . . "Weight gain has been observed with atypical antipsychotic uses.").

24. On information and belief, the physiological relationship between antipsychotic drug product use and patient weight is complex and poorly understood.

25. On information and belief, antipsychotic drug products exert different physiological effects relating to weight.

26. There is a need for drug products that are effective antipsychotics but that do not cause undesirable side effects, such as weight gain.

U.S. Patent No. 9,815,827

27. The ’827 patent, entitled “Agent for Treatment of Schizophrenia,” issued on November 14, 2017 and names Mitsutaka Nakamura, Masaaki Ogasa, and Shunsuke Sami as inventors.

28. By assignment, plaintiff Sumitomo owns all right, title, and interest in and to the ’827 patent.

29. Plaintiff Sunovion is the exclusive licensee to the ’827 patent in the United States.

30. Plaintiff Sunovion is the holder of approved New Drug Application (“NDA”) No. 200603 for lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg), which are sold in the United States under the registered trademark Latuda®.

31. In conjunction with NDA No. 200603, Sunovion has listed with the FDA ten patents for Latuda®. The listed patents are U.S. Patent Nos. 5,532,372, 8,729,085, 8,883,794, 9,174,975, 9,259,423, 9,555,027, 9,815,827, 9,827,242, RE45573, and 9,907,794. The FDA has published these ten patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.” The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the FFDCA.

32. Latuda®, or approved methods of using Latuda®, are covered by at least one claim of the ’827 patent listed in the Orange Book.

33. The ’827 patent is directed to methods of treating patients, including those with schizophrenia or manic depressive psychosis, with an antipsychotic without a clinically significant weight gain. The methods of treatment disclosed in the ’827 patent accomplish this through the oral administration of a particular dose, 20 mg to 120 mg, of lurasidone or a pharmaceutically acceptable salt of lurasidone (e.g., lurasidone hydrochloride) such that the

patient does not experience clinically significant weight gain for specific periods of time, including after six weeks of administration. Administration of such specific doses, and for such specific periods of treatment, result in a patient not experiencing clinically significant weight gain, which was not well understood, routine, or a conventional technique in the art.

Claims 40 and 43 of the '827 patent are illustrative and recite:

> 40. A method of treating a patient with an antipsychotic without a clinically significant weight gain, comprising:
>
> orally administering once daily to the patient a pharmaceutical composition comprising 20 to 120 mg of (1R, 2S, 3R, 4S)-N-[(1R, 2R)-2-[4-(1,2-benzoisothiazol-3-ly)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof as the sole active ingredient such that the patient does not experience a clinically significant weight gain.
>
> 43. The method of claim 41, wherein the administering is conducted such that the patient does not experience a clinically significant weight gain after six weeks of administration.

('827 patent, Cls. 40, 43.)

34. The claimed elements of exemplary claims 40 and 43 are found in the Latuda® Prescribing Information.

35. The Latuda® Prescribing Information describes Latuda® as "an atypical antipsychotic belonging to the chemical class of benzisothiazol derivatives." (Latuda® Prescribing Information (3/2018) at Section 11.)

36. The Latuda® Prescribing Information states "LATUDA tablets are intended for oral administration only. Each tablet contains 20 mg, 40 mg, 60 mg, 80 mg, or 120 mg of lurasidone hydrochloride." (Latuda® Prescribing Information (3/2018) at Section 11; *see also id.* at Section 3.)

37. The Latuda® Prescribing Information describes Latuda® as indicated for treatment of adult and adolescent patients age 13 to 17 years with schizophrenia, monotherapy treatment of adult and pediatric patients age 10 to 17 years with major depressive episodes associated with bipolar I disorder (bipolar depression), and adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression). (Latuda® Prescribing Information (3/2018) at Section 1.)

38. It further describes the dosage and administration for Latuda®. With respect to adult patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 160 mg per day . . . The maximum recommended dose is 160 mg per day." (Latuda® Prescribing Information (3/2018) at Section 2.1.) With respect to adolescent patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 80 mg per day . . . The maximum recommended dose is 80 mg per day." (*Id.*)

39. With respect to adults with depressive episodes associated with bipolar I disorder, the Latuda® Prescribing Information states "the recommended starting dose of LATUDA in adults is 20 mg given once daily as monotherapy or as adjunctive therapy with lithium or valproate. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 20 mg per day to 120 mg per day as monotherapy or as adjunctive therapy with lithium or valproate . . . The maximum recommended dose, as monotherapy or as adjunctive therapy with lithium or valproate, is 120 mg per day." (Latuda® Prescribing Information

(3/2018) at Section 2.2.) With respect to pediatric patients with depressive episodes associated with bipolar I disorder, the Latuda® Prescribing Information states that "[t]he recommended starting dose of LATUDA is 20 mg given once daily as monotherapy. Initial dose titration is not required. The dose may be increased after one week based on clinical response. LATUDA has been shown to be effective in a dose range of 20 mg per day to 80 mg per day as monotherapy . . . . The maximum recommended dose is 80 mg per day." (*Id.*)

40. When 20 mg to 120 mg of Latuda® is orally administered to patients, they do not experience a clinically significant weight gain. For example, the Latuda® Prescribing Information describes the following:

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Schizophrenia

Adults

Pooled data from short-term, placebo-controlled schizophrenia studies are presented in Table 9. The mean weight gain was +0.43 kg for LATUDA-treated patients compared to -0.02 kg for placebo-treated patients. Change in weight from baseline for olanzapine was +4.15 kg and for quetiapine extended-release was +2.09 kg in Studies 3 and 5 *[see Clinical Studies (14.1)]*, respectively. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 4.8% for LATUDA-treated patients and 3.3% for placebo-treated patients.

Table 9: Mean Change in Weight (kg) from Baseline in Adult Schizophrenia Studies

		LATUDA				
	Placebo (n=696)	20 mg/day (n=71)	40 mg/day (n=484)	80 mg/day (n=526)	120 mg/day (n=291)	160 mg/day (n=114)
All Patients	-0.02	-0.15	+0.22	+0.54	+0.68	+0.60

In the uncontrolled, longer-term schizophrenia studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.69 kg at week 24 (n=755), -0.59 kg at week 36 (n=443) and -0.73 kg at week 52 (n=377).

Adolescents

Data from the short-term, placebo-controlled adolescent schizophrenia study are presented in Table 10. The mean change in weight gain was +0.5 kg for LATUDA-treated patients compared to +0.2 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.3% for LATUDA-treated patients and 4.5% for placebo-treated patients.

Table 10: Mean Change in Weight (kg) from Baseline in the Adolescent Schizophrenia Study

		LATUDA	
	Placebo (n=111)	40 mg/day (n=109)	80 mg/day (n=104)
All Patients	+0.2	+0.3	+0.7

Bipolar Depression

Adults

Monotherapy

Data from the adult short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression study are presented in Table 11. The mean change in weight gain was +0.29 kg for LATUDA-treated patients compared to -0.04 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 2.4% for LATUDA-treated patients and 0.7% for placebo-treated patients.

Table 11: Mean Change in Weight (kg) from Baseline in the Adult Monotherapy Bipolar Depression Study

		LATUDA	
	Placebo (n=151)	20 to 60 mg/day (n=143)	80 to 120 mg/day (n=147)
All Patients	-0.04	+0.56	+0.02

Patients were randomized to flexibly dosed LATUDA 20 to 60 mg/day, LATUDA 80 to 120 mg/day, or placebo

In the uncontrolled, open-label, longer-term bipolar depression study, patients who received LATUDA as monotherapy in the short-term and continued in the longer-term study had a mean change in weight of -0.02 kg at week 24 (n=130).

Adjunctive Therapy with Lithium or Valproate

Data from the adult short-term, flexible-dosed, placebo-controlled adjunctive therapy bipolar depression studies are presented in Table 12. The mean change in weight gain was +0.11 kg for LATUDA-treated patients compared to +0.16 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.1% for LATUDA-treated patients and 0.3% for placebo-treated patients.

Table 12: Mean Change in Weight (kg) from Baseline in the Adult Adjunctive Therapy Bipolar Depression Studies

	Placebo (n=307)	LATUDA 20 to 120 mg/day (n=327)
All Patients	+0.16	+0.11

Patients were randomized to flexibly dosed LATUDA 20 to 120 mg/day or placebo as adjunctive therapy with lithium or valproate.

In the uncontrolled, open-label, longer-term bipolar depression study, patients who were treated with LATUDA, as adjunctive therapy with either lithium or valproate in the short-term and continued in the longer-term study, had a mean change in weight of +1.28 kg at week 24 (n=86).

(Latuda® Prescribing Information (3/2018) at Section 5.6.)

41. The change in weight results shown in Tables 9 and 11 reflect the change in weight after six weeks of administration of Latuda® as described in short-term, placebo-controlled schizophrenia and short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression studies, respectively, described in the Latuda® Prescribing Information. (*See also*

Latuda® Prescribing Information (3/2018) at Section 14.) The label also describes the weight gain seen in patients from longer term, open-label studies. (Latuda® Prescribing Information (3/2018) at Section 5.6.)

42. The therapeutic use of Latuda® represents an improvement over prior art methods of treating patients with an antipsychotic drug product, including those patients with schizophrenia and bipolar disorder.

U.S. Patent No. 9,907,794

43. The '794 patent issued March 6, 2018 and names Kazuyuki Fujihara as the inventor.

44. By assignment, plaintiff Sumitomo owns all right, title, and interest in and to the '794 patent.

45. Plaintiff Sunovion is the exclusive licensee to the '794 patent in the United States.

46. Latuda® tablets are covered by at least one claim of the '794 patent listed in the Orange Book.

47. The claims of the '794 patent are directed to tablets containing between 20 mg and 120 mg of lurasidone hydrochloride.

48. Claims 1 and 15 of the '794 patent are illustrative and recite:

> 1. A tablet for oral administration, comprising:
> from 20 mg to 120 mg of N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R, 2'S, 3'R, 4'S)-2,3-bicyclo[2,2, 1]heptane-dicarboxyimide hydrochloride (lurasidone) as an active ingredient;
> a pregelatinized starch;
> a water-soluble excipient;
> a water-soluble polymer binder; and
> a lubricant,
> wherein the tablet includes lurasidone at a content ratio of 20 to 45% (wt/wt);
> wherein the tablet has a dissolution rate of 80% or more at 30 minutes as measured according to Japanese Pharmacopoeia, Dissolution test, Method 2, where the tablet is

subjected to the Dissolution test using paddle rotation at a rotation rate of 50 rpm in 900 mL of a diluted McIlvaine buffer having a pH of 3.8 to 4.0;
wherein the tablet has a similar dissolution profile to a second tablet comprising from 20 mg to 120 mg of lurasidone,
wherein similarity of the dissolution profiles is exhibited by the tablet and a second tablet having a similarity factor f2 value of 50 or more,
wherein the tablet and the second tablet are prepared according to the same method, and comprise the same ratio of lurasidone, pregelatinized starch, water-soluble excipient, water-soluble polymer binder, and lubricant, and the second tablet has a different lurasidone content than the tablet.

('794 patent, Cl 1.)

15. A tablet for oral administration, comprising:
granules comprising:
from 20 mg to 120 mg of N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R, 2'S, 3'R, 4'S)-2,3-bicyclo[2,2,1]heptane-dicarboxyimide hydrochloride (lurasidone) as an active ingredient;
a pregelatinized starch;
a water-soluble excipient; and
a water-soluble polymer binder, and
a lubricant blended with the granules,
wherein the tablet includes lurasidone at a content ratio of 20 to 45% (wt/wt);
wherein the tablet has a dissolution rate of 80% or more at 30 minutes as measured according to Japanese Pharmacopoeia, Dissolution test, Method 2, where the tablet is subjected to the dissolution test using paddle rotation at a rotation rate of 50 rpm in 900 mL of a diluted McIlvaine buffer having a pH of 3.8 to 4.0;
wherein the tablet has a similar dissolution profile to a second tablet comprising from 20 mg to 120 mg of lurasidone,
wherein similarity of the dissolution profiles is exhibited by the tablet and a second tablet having a similarity factor f2 value of 50 or more,
wherein the tablet and the second tablet are prepared according to the same method, and comprise the same ratio of lurasidone, pregelatinized starch, water-soluble excipient, water-soluble polymer binder, and lubricant, and the second tablet has a different lurasidone content than the tablet.

('794 patent, Cl. 15.)

ACTS GIVING RISE TO THIS ACTION

49. On information and belief, Alkem submitted to the FDA ANDA No. 212244 under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg,

and 120 mg) (Alkem's "Proposed ANDA Product") prior to the expiration of the Asserted Patents. On information and belief, ANDA No. 212244 contains data from bioavailability or bioequivalence studies for such tablets.

50. On information and belief, Alkem sent a letter to Plaintiffs regarding the '827 and '794 patents ("Alkem's Notice Letter"), purporting to be a notice pursuant to Section 505(j)(2)(B)(i-iv) of the FFDCA. Alkem's Notice Letter purports to inform Plaintiffs that Alkem's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Alkem's Notice Letter bears the date August 27, 2018.

51. Plaintiff Sunovion received Alkem's Notice Letter on August 28, 2018.

52. Plaintiff Sumitomo received Alkem's Notice Letter on August 30, 2018.

53. Plaintiffs commenced this action within 45 days after receiving Alkem's Notice Letter.

54. On information and belief, Alkem's proposed label for its Proposed ANDA Product ("Proposed Alkem Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and/or depressive episodes associated with Bipolar (I) Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On information and belief, the Proposed Alkem Label will instruct physicians and healthcare providers to administer Alkem's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and/or depressive episodes associated with bipolar I disorder (bipolar depression).

55. On information and belief, the Proposed Alkem Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg,

60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in the Proposed Alkem Label demonstrate that patients receiving Latuda® and/or Alkem's Proposed ANDA Product do not experience clinically significant weight gain.

56. On information and belief, the Proposed Alkem Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and/or manic depressive psychosis, without the patient experiencing clinically significant weight gain.

57. On information and belief, the Proposed Alkem Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and/or manic depressive psychosis, without the patient experiencing clinically significant weight gain.

58. On information and belief, such administration will directly infringe the '827 patent's claims.

59. On information and belief, Alkem became aware of the '794 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

60. On information and belief, Alkem's Proposed ANDA Product will directly infringe one or more claims of the '794 patent either literally or under the doctrine of equivalents.

61. On information and belief, following approval of ANDA No. 212244, Alkem will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in New Jersey.

62. Since receiving Alkem's Notice Letter, Plaintiffs attempted to procure a copy of ANDA No. 212244 from Alkem. Because the terms of the proposed Offer for Confidential Access would not allow Plaintiffs to meaningfully process the information contained in the ANDA, Plaintiffs could not agree to the terms of the original Offer. On October 8, 2018, Alkem produced a copy of its ANDA No. 212244 after the parties were able to reach an agreement on the Offer for Confidential Access. The timing of Alkem's production, however, has not allowed Plaintiffs sufficient opportunity to complete their investigation into Alkem's ANDA No. 212244 prior to the expiry of the period set forth in 21 U.S.C. § 355(j)(5)(B)(iii). *See Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359 (Fed. Cir. 2000).

63. Plaintiffs, thus, resort to the judicial process and the aid of discovery to confirm their allegations of infringement and to present the Court evidence that Alkem's proposed lurasidone hydrochloride tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg fall within the scope of one or more claims of the '827 and '794 patents.

64. Because they have not had sufficient opportunity to complete their investigation of ANDA No. 212244, Plaintiffs allege the causes herein based primarily on the representations contained in Alkem's Notice Letter and the other facts alleged herein.

COUNT I

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Alkem's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

65. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

66. Alkem submitted its ANDA No. 212244 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting such

application, Alkem has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

67. The commercial manufacture, importation, use, sale, or offer for sale of Alkem's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

68. On information and belief, Alkem became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

69. On information and belief, Alkem will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Alkem will engage in such activities upon the FDA's final approval of Alkem's ANDA.

70. On information and belief, Alkem knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

71. The commercial manufacture, importation, use, sale, or offer for sale of Alkem's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

72. Unless and until Alkem is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

73. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Alkem's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT II

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271(b) and/or (c) by Alkem's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

74. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

75. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

76. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

77. On information and belief, Alkem's Proposed ANDA Product is covered by the claims of the '827 patent.

78. Alkem has actual knowledge of the '827 patent.

79. On information and belief, Alkem became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

80. On information and belief, Alkem has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

81. On information and belief, Alkem will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Alkem will engage in such activities upon the FDA's final approval of Alkem's ANDA.

82. The commercial manufacture, use, sale, offer for sale, and/or importation of Alkem's Proposed ANDA Product will induce the actual infringement of the '827 patent.

83. On information and belief, Alkem knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product will actively induce the actual infringement of the ’827 patent.

84. On information and belief, Alkem will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the ’827 patent.

85. On information and belief, Alkem will encourage another’s infringement of the ’827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the ’827 patent.

86. Alkem’s act of infringement will be done with the knowledge of the ’827 patent and with the intent to encourage infringement.

87. The foregoing actions by Alkem will constitute active inducement of the infringement of the ’827 patent.

88. On information and belief, Alkem knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the ’827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

89. On information and belief, Alkem knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

90. The commercial manufacture, use, sale, offer for sale, and/or importation of Alkem’s Proposed ANDA Product will contribute to the actual infringement of the ’827 patent.

91. On information and belief, Alkem knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

92. The foregoing actions by Alkem will constitute contributory infringement of the '827 patent.

93. On information and belief, Alkem intends to, and will, actively induce and contribute to the infringement of the '827 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon final approval.

94. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed ANDA Product by Alkem will induce and/or contribute to infringement of the '827 patent.

95. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

96. Unless Alkem is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

97. On information and belief, despite having actual notice of the '827 patent, Alkem continues to prepare to actively induce and/or contribute to infringement of the '827 patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

Infringement of the '794 Patent Under 35 U.S.C. § 271(e)(2) by Alkem's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

98. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

99. Alkem submitted ANDA No. 212244 to the FDA under Section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting this application, Alkem has committed an act of infringement of the '794 patent under 35 U.S.C. § 271(e)(2)(A).

100. The commercial manufacture, importation, use, sale, or offer for sale of Alkem's Proposed ANDA Product will constitute an act of infringement of the '794 patent.

101. On information and belief, Alkem became aware of the '794 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

102. On information and belief, Alkem will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Alkem will engage in such activities upon the FDA's final approval of ANDA No. 212244.

103. On information and belief, Alkem knows or should know that its commercial manufacture, use, offer for sale, sale and/or importation of its Proposed ANDA Product will directly infringe one or more claims of the '794 patent.

104. The commercial manufacture, use, offer for sale, sale or importation of Alkem's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

105. Unless and until Alkem is enjoined from infringing the '794 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

106. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia,* an order of this Court stating that the effective date of approval for Alkem's ANDA be a date that is not earlier than the expiration date of the '794 patent, as well as any extensions thereof.

COUNT IV

Declaratory Judgment of Infringement of the '794 Patent Under 35 U.S.C. § 271(a) by Alkem's Proposed Generic Lurasidone Hydrochloride Tablets 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

107. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

108. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

109. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

110. The commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed ANDA Product described in ANDA No. 212244 will constitute an act of direct infringement of one or more claims of the '794 patent.

111. On information and belief, Alkem will engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed ANDA Product described in ANDA No. 212244 immediately and imminently upon final approval of such ANDA.

112. The foregoing actions by Alkem will constitute infringement of the '794 patent.

113. Alkem will commit those acts of infringement without license or authorization.

114. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Alkem's Proposed ANDA Product described in ANDA No. 212244 by Alkem will infringe the '794 patent.

115. Unless Alkem is enjoined from infringing the '794 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) That a judgment be entered that Alkem has infringed the '827 and '794 patents under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA No. 212244 under Section 505(j) of the FFDCA, and the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Alkem's Proposed ANDA Product will constitute an act of infringement of the '827 and '794 patents;

B) That a judgment be entered declaring that the '827 and '794 patents have not been proven invalid or unenforceable;

C) That an Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Alkem's ANDA shall be a date which is not earlier than the expiration dates of the '827 and '794 patents as extended by any applicable period of exclusivity;

D) That an injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B) and/or § 283 permanently enjoining Alkem, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Alkem or acting on Alkem's behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '827 and '794 patents;

E) That a judgment be entered declaring that if Alkem engages in the commercial manufacture, use, offer to sell, sale, or importation of Alkem's generic products disclosed in its ANDA prior to the expiration of the '827 and '794 patents, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

F) That a judgment be entered declaring that if Alkem engages in the commercial manufacture, use, offer to sell, sale, or importation of the Proposed ANDA Product disclosed in its ANDA prior to the expiration of the '827 and '794 patents, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C) and/or § 284, increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

G) That a judgment be issued pursuant to 28 U.S.C. § 2201 declaring that if Alkem, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Alkem or acting on Alkem's behalf, engage in the commercial manufacture, use, offer to sell, sale, and/or importation of Alkem's Proposed ANDA Product prior to the expiration of the '827 and '794 patents, it will constitute an act of infringement of the '827 and '794 patents under 35 U.S.C. §§ 271(a), (b) and/or (c);

H) That a judgment be entered that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

I) An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

J) Such other and further relief as the Court may deem just and proper.

Dated: October 9, 2018

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